

### **REMARKS**

This Response is submitted in response to the Office Action mailed on November 14, 2003.

Claims 8-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,317,838 ("*Cherukuri*"). Applicants respectfully submit that the cited reference fails to teach or arguably suggest a number of the features of the claimed invention and that the above-mentioned rejection is improper for reasons set forth below.

The present invention provides a product including a medicament comprising a consumable center and a coating. The coating comprises the medicament and surrounds the consumable center. In addition, the coating comprises at least 50% by weight of the product. The invention further provides a product including a medicament comprising a consumable tableted center and a coating. The coating comprises the medicament and at least substantially surrounds the tableted center. In addition, the coating comprises at least 50% by weight of the product.

*Cherukuri* discloses a method of applying a coating to a comestible or solid center. According to *Cherukuri*, the solid center can include "pills, tablets or other solid dosage forms for medicinal or therapeutic use". See Col. 5, lines 55-60 cited by the Office Action. Therefore, if a medicament is used in *Cherukuri*, the medicament is limited to the solid center. Applicants' claims require a medicament in the coating. *Cherukuri* lacks any disclosure or suggestion to motivate one of ordinary skill in the art to provide a product containing a coating which includes a medicament. Thus, this is one claimed element that is not disclosed or suggested by *Cherukuri*.

Furthermore, *Cherukuri* discloses the steps of applying the coating syrup and dusting mix to build up a desired coating weight and thickness on the centers. The Office Action acknowledges that *Cherukuri* is silent as to the particular amount of the coating (See Office action on page 3) but states that a coating comprising at least 50% by weight of the product could be readily determined by one skilled in the art through routine experimentation. A particular parameter must first be recognized by the cited reference as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or

workable ranges of said variable might be characterized as routine experimentation. In *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), the prior art did not recognize that the treatment capacity of a wastewater treatment device was a function of the optimized tank volume to contractor ratio parameter, and, therefore, the parameter was not recognized in the art to be a result-effective variable to be optimized by routine experimentation. See MPEP §2144.05 II. B. Likewise, *Cherukuri* does not recognize that thick coatings absorb more moisture than thinner coatings allowing the coating to comprise, for example, merely a matte finish instead of a shellac or other finishing or shiny layer. Coatings comprising at least 50% by weight of the product in the present invention, thereby, prevent degradation of the product and increase shelf-life. See Applicant's Specification, page 16, paragraph 2. The highest "desired" amount of coating disclosed in *Cherukuri* is 35% by weight of the product with no suggestion that this level of thickness absorbs more moisture. See Col. 4, lines 29-34. Therefore, there is no disclosure or suggestion in *Cherukuri* that the coating comprises at least 50% by weight of the product. This is another claimed element missing from *Cherukuri*.

Applicants respectfully submit that *Cherukuri* fails to disclose or suggest the claimed invention. Accordingly, Applicants respectfully submit that this rejection be withdrawn.

Claims 8 and 16 have been amended for clarification purposes only. The amendments are non-narrowing and, therefore, Applicants do not intend to disclaim any subject matter in view of the amendments. Moreover, these amendments do not add new matter.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

  
BY \_\_\_\_\_

Robert M. Barrett  
Reg. No. 30,142  
P.O. Box 1135  
Chicago, Illinois 60690-1135  
Phone: (312) 807-4204  
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